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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,732	07/25/2001	Joseph Atabekov	0933-0169P	5590
2292	7590	01/16/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/911,732	ATABEKOV ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	David A. Lambertson	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 October 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 19,20,23,24,29-31,33,34,36,38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 19,23,24,29-31,33,34 and 40 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 20,36,38,41 and 42 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. 09/424,793.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 1, 2003 has been entered.

Receipt is acknowledged of a reply to the previous Office Action, filed October 1, 2003. Amendments were made to the claims. Claims 1-18, 21-22, 25-28, 32, 35, 37 and 39 were cancelled, and new claims 40-43 were added. Specifically, the nature of the invention in claims 19, 23, 24, 29-31, 33, 34 and newly added claim 40 was changed from a nucleic acid (original) to a process (new); therefore, newly submitted claims 19, 23, 24, 29-31, 33, 34 and 40 are directed to an invention (i.e., a process) that is independent or distinct from the invention originally claimed (i.e., a nucleic acid). Applicant is reminded that it is improper to change the nature of the invention when filing an RCE, and that such a change will result in the affected claims being withdrawn by original presentation.

Since applicant has received an action on the merits for the originally presented invention (i.e., the nucleic acid), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19, 23, 24, 29-31, 33, 34 and 40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 19, 20, 23, 24, 29-31, 33, 34, 36, 38 and 40-43 are pending in the instant application. Claims 1-18, 21-22, 25-28, 32, 35, 37 and 39 are cancelled. Claims 19, 23, 24, 29-31, 33, 34 and 40 are withdrawn from consideration as being directed to a non-elected invention. Claims 20, 36, 38 and 41-43 are under consideration in the instant application, and an Office Action on the Merits regarding these claims is presented herein. Any rejection of record in the previous Office Action, mailed July 1, 2003, that is not addressed in this action has been withdrawn.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 36, 38 and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a recombinant nucleic acid for expressing two or more genes of interest in a polycistronic message, wherein the recombinant nucleic acid comprises an internal ribosome entry sequence (IRES) of plant viral origin. The claims read on a broad genus of IRES that are of plant viral origin which must have a structure-function relationship that allows the expression of a polycistronic message.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice

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or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a recombinant nucleic acid comprising an IRES of plant viral origin by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings regarding a recombinant nucleic acid comprising an IRES that originates from a particular plant virus, that virus being crTMV (the crucifer infecting tobamovirus). The specification does not teach a structure-function relationship for this particular IRES that would describe another IRES from a completely different plant-specific virus. Thus, the skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only describes a single IRES of plant virus origin without disclosing a structure-function relationship that would describe additional IRES of plant viral origin.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of IRES of plant viral origin by disclosing structural or functional features of a plant virus IRES so that one of skill in the art could envision the claimed invention. In fact, the prior art discloses that the particular IRES

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described in the instant specification (i.e., the crTMV IRES) is unique, even with respect to plant viruses that are within the same genus (see for example Ivanov et al.; IDS reference; see entire document; henceforth Ivanov). For example, crTMV is within the same genus as TMV UI, which does not have an IRES (see for example the Abstract and the Introduction [first full paragraph, page 33] of Ivanov). Thus, it is clear from the prior art that the skilled artisan cannot envision other IRES of plant viral origin because even viruses that are closely related to the virus from which the instantly described IRES originates lack an IRES. Thus, the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of plant viral IRES to be placed in the recombinant nucleic acid of the claimed invention. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 20, 36, 38 and 41-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an IRES of crTMV origin, does not reasonably provide enablement for any IRES of plant viral origin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Electronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

**Nature of the invention.** The nature of the invention is a recombinant nucleic acid for expressing two or more genes of interest as a polycistronic message. The recombinant nucleic acid contains a number of elements, including a promoter, the genes of interest, and an IRES of plant viral origin. The IRES is the inventive portion of the recombinant nucleic acid, thus the skilled artisan must be able to make and use such an IRES.

**Scope of the invention.** The scope of the invention is very broad, encompassing a vast number of IRES of plant viral origin, many of which have not been described in either the instant specification or the prior art (see the Written Description rejection set forth above). The skilled artisan must be able to make and use the broad scope of plant virus IRES in order to make and use the invention.

**Number of working examples and Guidance provided by applicant.** The instant specification provides guidance and examples with regard to a single IRES of plant viral origin, the crTMV IRES. The instant specification does not describe a structure-function

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relationship for the crTMV IRES that would allow the skilled artisan to make and use another IRES of plant viral origin. In fact, the skilled artisan would not know of any other IRES of plant viral origin to be used in the instant invention by consulting the instant specification. Therefore, the skilled artisan cannot rely on the instant specification to make and use any IRES of plant virus origin other than the crTMV IRES.

**State of the art.** When consulting the prior art, the skilled artisan would again be unable to use any IRES of plant viral origin besides the crTMV IRES. This is because the prior art only serves to confirm the status of the crTMV IRES as unique, even within the genus of viruses to which it belongs (see for example Ivanov; see entire document, especially the Abstract and the Introduction [first full paragraph, page 33]). Thus, the prior art establishes that it is unpredictable to make or use any IRES of plant viral origin besides the crTMV IRES because it is not even known which viruses have or do not have an IRES. This is exemplified by the fact that two closely related viruses, crTMV and TMV UI, do not both have IRES or mechanisms for their use. As a result, the skilled artisan cannot rely on the prior art to make and use the full scope of the claimed invention.

**Unpredictability of the art and Amount of experimentation required.** The full scope of the invention requires a great deal of empirical experimentation that is both undue and highly unpredictable. In order to make and use the full scope of the invention, the skilled artisan would necessarily have to identify any other IRES of plant viral origin because neither the instant specification nor the prior art describes the full scope of plant-virus IRES. The unpredictability of the full scope of the instantly claimed invention is exemplified by the fact that two closely related viruses (in that they belong to the same genus), TMV UI and crTMV, do not share a common mechanism using IRES (see for

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example the Abstract and the Introduction [first full paragraph, page 33] of Ivanov).

Thus, the IRES of plant viral origin described by the instant specification is unique, and cannot be predictably related to other IRES of plant viral origin. In this sense, the instant claims merely represent an invitation to trial and error experimentation with the hopes of discovering a new IRES of plant viral origin. As such, the instant claims cannot be enabled.

In conclusion, the broad scope of the instantly claimed invention is not enabled because the skilled artisan cannot make and use any IRES of plant viral origin. Both the instant specification and the prior art fail to indicate how the single example provided in the instant specification can be translated into the use of any plant-virus IRES; in fact, the prior art supports the uniqueness of the single example, even with respect to related viruses. Thus, the breadth of the claims merely proffers an invitation to empirical and unpredictable experimentation, which dictates that the claimed invention is not enabled.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 20, 36, 38 and 41-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 6, 9 and 10 of US Patent No. 6,376,745 (henceforth the '745 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20, 36, 38 and 41-43 of the instant application describe generic recombinant nucleic acids comprising any plant-virus IRES, which are anticipated by the specific claims of the '745 patent. In particular, the '745 patent describes generic recombinant nucleic acids comprising an IRES of a tobamovirus moving protein gene, which falls within the broad scope of the instantly claimed invention. Since the claims of the '745 patent fall within the broad genus of the instant claims, they anticipate the instant claims and are therefore subject to obviousness-type double patenting.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the patent. Also, if both patents are issued and the patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the '745 patent, then two different assignees would hold a patent to the same claimed invention and thus improperly there would be possible harassment by multiple assignees.

***Allowable Subject Matter***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703)

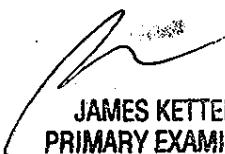
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308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.  
AU 1636



JAMES KETTER  
PRIMARY EXAMINER